Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effect of Intravenous Versus Intraincisional Antibiotics on Surgical Site Infection and Related Complications in Patients with Head and Neck Skin Cancer : A Randomized Controlled Trial (RCT)

Protocol summary

Study aim

To evaluate the effect of intravenous antibiotic prophylaxis versus intra incisional antibiotic prophylaxis on reducing SSIs and their related complications in patients with head and neck skin cancer undergoing surgery . To compare local and systemic adverse effects in patients receiving intra-incisional prophylactic antibiotics with those receiving intravenous prophylactic antibiotics.

Design

A randomized, single-blind, parallel-group clinical trial conducted on 42 patients.

Settings and conduct

A randomized controlled clinical trial conducted to evaluate and compare the effect of intravenous antibiotic prophylaxis versus intra-incisional antibiotic prophylaxis on reducing surgical site infections and related complications in patients with head and neck skin cancer. Patients with head and neck skin cancer who are admitted for surgical treatment at Farhikhtegan Hospital, Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with head and neck skin cancer who are candidates for surgical treatment. Written informed consent to participate in the study. No history of allergy to the antibiotics used in the study. Exclusion criteria : Patients with systemic diseases that affect wound healing (uncontrolled diabetes).Patients with immunodeficiency.Patients who do not adhere to the prescribed treatment.

Intervention groups

Group 1 : A dose of intravenous antibiotic one hour before surgery, as the standard prophylactic protocol. Group 2 : The antibiotic locally at the surgical incision site during the operation as an intra-incisional prophylactic dose.

Main outcome variables

Incidence of SSI; Severity of complications; Length of hospital stay; Need for additional antibiotic therapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251116068008N1**
Registration date: **2026-05-05, 1405/02/15**
Registration timing: **prospective**

Last update: **2026-05-05, 1405/02/15**
Update count: **0**

Registration date

2026-05-05, 1405/02/15

Registrant information

Name
Hesan Abbasi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-11-22, 1405/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Intravenous Versus Intraincisional Antibiotics on Surgical Site Infection and Related Complications in Patients with Head and Neck Skin Cancer : A Randomized Controlled Trial (RCT)

Public title

Comparison of the effects of intravenous and systemic antibiotics in head and neck cancer surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with head and neck skin cancer undergoing surgery Having provided written informed consent to participate in the study With no history of allergy to the antibiotics used in the study

Exclusion criteria:

Patients with a history of systemic diseases affecting wound healing (such as uncontrolled diabetes) Individuals with immune deficiency Patients who have not adhered to the treatment protocol

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

In this randomized clinical trial, eligible patients who provide written informed consent will be randomly assigned in a 1:1 ratio to one of two groups: preoperative intravenous antibiotic and intra-incisional antibiotic administered during surgery. The random allocation sequence will be generated by a biostatistician using a computer-based random number generator and block randomization with blocks of size 4, in order to ensure a balanced distribution of patients between the two groups. For allocation concealment, the allocation code for each patient will be placed, according to the randomization list, in sequentially numbered, opaque, sealed envelopes that are impermeable to light. After a patient is enrolled in the study, the investigator responsible for recruitment will open the next envelope in sequence and assign the patient to the corresponding intervention group (intravenous or intra-incisional antibiotic). The biostatistician responsible for data analysis will remain blinded to the group allocation.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the nature of the intervention (intravenous antibiotic one hour before surgery versus intra incisional antibiotic during surgery), blinding of the surgeon and anesthetic team is not feasible and the intervention is open to the care providers. However, to reduce bias, all patients will be recorded in the database with anonymous group codes (Group A and Group B), and the statistician/data analyst will be blinded to the allocation when performing the final analysis (single-blind trial – data analyst). If feasible, assessment of surgical site infection during follow-up visits will be performed by an outcome assessor who is unaware of the patient's allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University, Tehran Medical Sciences Branch

Street address

No. 11 , Kowsar Residential houses, Kaboli Ave , Tehran Town

City

Tehran

Province

Tehran

Postal code

1631715634

Approval date

2026-02-01, 1404/11/12

Ethics committee reference number

IR.IAU.FARHIKHTEGAN.REC.1404.007

Health conditions studied

1

Description of health condition studied

surgical site infection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Incidence of surgical site infection at the incision site of head and neck skin cancer surgery within 30 days after

surgery, based on clinical assessment on postoperative days 1, 3, 7, and 30, considering signs of infection including incision site redness, discharge or pus, pain at the surgical site, wound dehiscence, fever above 38°C, need for readmission or additional treatment, and culture result if performed.

Timepoint
Postoperative days 1, 3, 7, and 30

Method of measurement
Clinical examination of the surgical incision site by a physician and completion of the wound status and complications follow-up form, including assessment of incision site redness, discharge or pus, pain at the surgical site, wound dehiscence, fever above 38°C, need for readmission or additional treatment, and culture result if performed.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Farhikhtegan hospital

Full name of responsible person
Hesan Abbasi

Street address
Shohadaye Hesarak Blvd , Hesarak , Tehran

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Tehran

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1477899679

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farhikhteganhospital@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Ehsanollah Rahimi Movaghar

Street address
North Sattari، Islamic Azad Univesity Square، Tehran، Iran

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Islamic Azad University Of Medical Science

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Hesan Abbasi

Position
Medical Student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Identified individual participant data, including demographic and clinical information, data related to the therapeutic intervention, wound status, postoperative complications, and occurrence of surgical site infection within 30 days after surgery. These data may be shared after removal of patients' identifying information and with respect for confidentiality, upon reasonable request by researchers and approval of the principal investigator.

When the data will become available and for how long
The access period for de-identified data and study documents will begin 6 months after publication of the final study results and will continue for 2 years. Access to the data will be subject to a reasonable request, approval by the principal investigator, and compliance with confidentiality principles.

To whom data/document is available
Researchers and faculty members affiliated with universities, research centers, and accredited scientific institutions may submit requests to access the de-identified data and study documents. Access will be granted after review of the research purpose, approval by the principal investigator, and commitment to confidentiality principles and use of the data solely for scientific and research purposes.

Under which criteria data/document could be used
The de-identified data and study documents may be used only for scientific, research, and educational purposes, systematic reviews, meta-analyses, and secondary analyses related to the study topic. Use of the data for commercial or advertising purposes, re-identification of participants, or disclosure of individual patient information is not permitted. Requirements for submitting a data access request include a written request, a clear statement of the research objective, submission of a proposal or data analysis plan, specification of the required data, commitment to confidentiality, agreement not to attempt re-identification of participants, use of the data only within the approved purpose, and approval by the principal investigator.

From where data/document is obtainable
Applicants requesting access to de-identified data or study documents may primarily submit their request by email to the principal investigator of the study. The request should include the applicant's introduction, institutional affiliation, research objective, type of data or documents requested, and data analysis plan. If needed, correspondence through the postal address of the relevant department or research center at Farhikhtegan Hospital, Tehran, will also be possible.

What processes are involved for a request to access data/document
The applicant should submit a written request to the principal investigator, including an institutional letter of introduction, the research objective, the proposal or data analysis plan, the type of data or documents requested, and a confidentiality agreement. Requests will be

reviewed by the principal investigator and, if necessary, by the ethics committee or the relevant academic authority. If approved, the de-identified data and related documents will be provided to the applicant after signing a data use agreement. The review and response process will usually be completed within 4 to 6 weeks after receipt of all required documents.

Comments